

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: TIMOTHY E. NIEDNAGEL  
BARNES & THORNBURG  
11 SOTUH MERIDIAN STREET  
INDIANAPOLIS IN 46204

PCT

WRITTEN OPINION

(PCT Rule 66)

Date of Mailing  
(day/month/year)

20 AUG 2001

Applicant's or agent's file reference

7175-64836

REPLY DUE

within ONE months  
from the above date of mailing

International application No.

PCT/US99/17877

International filing date (day/month/year)

06 AUGUST 1999

Priority date (day/month/year)

07 AUGUST 1998

International Patent Classification (IPC) or both national classification and IPC  
IPC(7):A 61F 13/00 and US Cl. 604/304

Applicant

HENLEY, ALAN WAYNE

1. This written opinion is the first (first, etc.) drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. ~~The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.4(d).~~

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 07 DECEMBER 2000

Name and mailing address of the IPEA/US

Counsellor of Patents and Trademarks  
Box PCT  
Washington, D.C. 20531

Facsimile No. (703) 305-9230

Authorized officer

KIM MARIE LEWIS

Telephone No. (703) 308-1191

WRITTEN OPINION

International application No.

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I. Basis of the opinion

1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed  
the description:  
pages 1-25, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the letter of
- ☒ the claims:  
pages 26-31, as originally filed  
pages NONE, as amended (together with any statement) under Article 19  
pages NONE, filed with the letter of
- ☒ the drawings:  
pages 1-21, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of
- ☒ the sequence listing part of the description:  
pages NONE, as originally filed  
pages NONE, filed with the demand  
pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the International application in printed form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE  
☒ the claims, Nos. NONE  
☒ the drawings, sheets/fig. NONE

5. ☐ This opinion has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".

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**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. statement**

Novelty (N)

Claims (Please See supplemental sheet) YES

Claims (Please See supplemental sheet) NO

Inventive Step (IS)

Claims (Please See supplemental sheet) YES

Claims (Please See supplemental sheet) NO

Industrial Applicability (IA)

Claims (Please See supplemental sheet) YES

Claims (Please See supplemental sheet) NO

**2. citations and explanations**

Claims 1, 17, 36 and 38 lack novelty under PCT Article 33(2) as being anticipated by Westaby et al. Claims 1, 17, and 38 Westaby et al. anticipates a wound irrigation device comprising a bandage configured to cover a wound (10) and to seal about the perimeter and providing a cavity over the wound, a fluid supply and a fluid drainage and fluid delivery and fluid drainage tubing.

Claim 38, although not stated it is inherent in the disclosure that a receptacle of some sort is connected to the fluid drainage line in order to collect the fluid drained from the wound.

Claims 3, 12-15, 21, 22, 37 and 39 lack an inventive step under PCT Article 33(3) as being obvious over Westaby et al. Claims 3 and 37, Westaby et al. teach that hydrogen peroxide may be supplied to wound. Westaby et al. fail to teach a liquid medication pump is coupled to the fluid supply. The examiner contends that the addition of medication to a patient intravenously or directly to a wound site via a pump is well known and modifying Westaby with a liquid medication pump would have been routine within the level of one having ordinary skill in the art. Claims 12, 13, 14, 15, 21 and 22 the dependent claims do not appear to contain any additional features, which in combination with the features of any claim to which they refer, add anything new or novel. More specifically, a pressure sensor, pressure sensor controller, and a display are well known features in the art, and the addition of such to a prior art device would only require routine skill in the art. Claim 39, Westaby et al. fail to teach a bendable wire in the tubing. Absent a critical teaching and a showing of unexpected results derived from the usage of such, the examiner contends that the bendable wire is an obvious design choice.

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Westaby et al. in view of Harvey. Claim 4, Westaby et al. fail to teach a vacuum pump connected to the (Continued on Supplemental Sheet)

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**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

The description is objected to as containing the following defect(s) under PCT Rule 66.2(a)(iii) in the form or contents thereof: page 8, line 22 "nebulizer output port 28" was previously designated with reference character 30; on page 10, the applicant designates "68" as a water trap, then refers to it as a pressure sensor on page 11; and on page 11, line 28, "selector valve 60" should read "selector valve 58".

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Sheet 10

Continuation of: Boxes I - VIII

TIME LIMIT:

The time limit set for response to a Written Opinion may not be extended. 37 CFR 1.484(d). Any response received after the expiration of the time limit set in the Written Opinion will not be considered in preparing the International Preliminary Examination Report.

V. 1. REASONED STATEMENTS:

The opinion as to Novelty was positive (YES) with respect to claims 2-16, 18-35, 37 and 39-44.

The opinion as to Novelty was negative (NO) with respect to claims 1, 17, 36 and 38.

The opinion as to Inventive Step was positive (YES) with respect to claims 2, 5-8, 16, 18, 19, 20, 23, 24-35 and 40-44.

The opinion as to Inventive Step was negative (NO) with respect to claims 1, 3, 4, 9-15, 17, 21, 22, 36-38, 39.

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-44.

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE.

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

fluid drainage. However, Harvey teaches it is well known to connect a vacuum pump to a fluid drainage line of a wound dressing in order to evacuate fluid from the wound. It would have been obvious to one having ordinary skill in the art to modify Westaby with the addition of a vacuum pump connected to the fluid drainage in order to evacuate fluid from the wound, as suggested by Harvey.

Claims 9-11 are an inventive step under PCT Article 33(3) as being obvious over Westaby et al. in view of Viesturs. Claim 9, Westaby et al. fail to teach an oxygen supply connected to the fluid supply. However, Viesturs teaches it is conventional in the art to connect an oxygen supply to the fluid supply of a wound dressing because of the healing effects associated with providing oxygen to body sores and wounds. It would have been obvious to one having ordinary skill in the art to modify the dressing of Westaby with the addition of an oxygen supply connected to the fluid supply of a dressing because of the healing effects associated with providing oxygen to body sores and wounds. Claims 10 and 11, the addition of other healing fluids such as air, as well as various valving configurations for selecting one or more fluids to be supplied to the wound is also considered an obvious design choice to one having ordinary skill in the art.

Claims 2, 5-8, 16, 18, 19, 20, 23, 24-35, and 40-44 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a wound treatment apparatus comprising the limitations claimed by the instant invention.

NEW CITATIONS  
US 28 09 828 A1 (WESTABY et al.) 21 September 1978, see Fig. 1.

US 4,969,881 A (VIESTURS) 13 November 1990, see the entire document.

US 3,568,675 A (HARVEY) 09 March 1971, see the entire document.